K062769

510(k) Summary

Submitter:	Radi Medical Systems AB Palmbladsgatan 10 SE-754 50 Uppsala, Sweden Phone:(+46) 18161000
Contact:	Mats Granlund
Date Prepared:	September 13, 2006
Proprietary Name:	PressureWire®
Common Name:	Pressure Guidewire
Classification Name:	Catheter Tip Pressure Transducer (21 CFR 870.2870) Product Code DXO
Predicate Devices:	PressureWire® Sensor, K031662 Safe-Cross Deflecting Catheter, K040481

DEC - 4 2006

Device Description
PressureWire® is a .014" guidewire with an integrated pressure and temperature sensor, together with a detachable cable for connection to a diagnostic computer.

Intended Use of the Device:
PressureWire® has the same intended use as the submitter's predicate device. PressureWire® is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a vessel. The signal output from the senor is used for calculation and presentation of any physiological parameters, functions or indices based on pressure or temperature, e.g. Fractional Flow Reserve (FFR).

Technological Characteristics:
PressureWire® is similar in basic material, design, construction and mechanical performance to the predicate device. The main modification is that the distal part has been coated with a hydrophilic coating.

Performance Data
Biocompatibility and performance testing indicate that PressureWire® satisfies safety and performance requirements of the device specifications and do not raise additional safety issues.

Conclusion
On the basis of the testing conducted, it may be concluded that PressureWire® satisfies specified safety and performance requirements. PressureWire® is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 4 2006

Radi Medical Systems
c/o Mats Granlund
Director, Quality & Regulatory Affairs
Palmbladsgatan 10
Uppsala, Sweden SE-754 50

Re: K062769
Trade/Device Name: PressureWire®
Regulation Number: 21 CFR 870.2870
Regulation Name: Catheter tip pressure transducer
Regulatory Class: II
Product Code: DXO, DQX
Dated: October 25, 2006
Received: October 26, 2006

Dear Mr. Granlund:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K062769

Device Name: PressureWire®

Indications for Use: PressureWire® is indicated to direct a catheter through a blood vessel and to measure physiological parameters in the coronary and peripheral blood vessels.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062769